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**Remarks**

Upon entry of the amendment, claims 24-36, 39-43, 46-50, 53-57, and 60-73 will be pending. Claims 11, 12, 16, 37-38, 44-45, 51-52, and 58-59 have been canceled without prejudice or disclaimer. Claims 36, 40-43, 47-50, 54-57, and 61-63 have been amended to more clearly claim the subject matter Applicants regard as the invention. Support for the amended claims is found throughout the specification as filed. Thus, no new matter has been introduced.

In addition, Applicants have amended the specification at page 11 by deleting the single-spaced text found at lines 12-43. The deleted text is merely an illustration of the disclosure at page 11, lines 8-9, therefore, its deletion is not new matter.

**1. Interview With Examiner Marschel**

Applicants thank Examiner Marschel for the telephonic interview dated September 5, 2002. The utility rejection of claims 24-73 and the enablement rejection of claims 36-63 was discussed in the interview.

Specifically, in regard to the utility rejection of claims 24-73, the undersigned addressed the Examiner's concern that it was not allegedly evident that a control tissue was used in determining that the gene encoding the polypeptides of SEQ ID NO:73 is specifically expressed in adrenal gland tumor tissue. *See*, Paper No.12, page 7, last paragraph to page 8, first paragraph. The undersigned pointed out that Applicants assessed the expression of the polynucleotides of the claimed invention in many tissues including normal adrenal gland tissue. For example, the specification at page 75, lines 14-21; and Tables 2 and 4 found at pages 77-78 and 80-86, respectively, illustrate some of the many tissues of which expression was determined. In particular, the undersigned pointed out that Applicants assessed the expression of the polynucleotide of SEQ ID NO:33 (which encodes the polypeptide of SEQ ID NO:73 (*see*, Table 1, row 3, at page 42 of the specification)) in both normal human adrenal gland tissue and human adrenal gland tumor tissue. Based on this assessment, no expression was observed in normal human adrenal gland tissue. In contrast, expression was observed in human adrenal gland tumor tissue. This fact is also stated in the Declaration of George Komatsoulis Under 37 C.F.R. § 1.132 (submitted herewith as Exhibit A). Examiner Marschel had indicated that if, in fact, Applicants had assessed the expression of the gene encoding the claimed polypeptides in "control" tissues such as normal adrenal gland tissue, the utility rejection would be obviated.

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AM, 1-8-03

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Further, in regard to the enablement rejection of claims 36-63, the undersigned suggested that the claim language "wherein said first polypeptide is capable of generating or selecting an antibody that specifically binds said second polypeptide," be deleted from independent claims 36, 43, 50, and 57 to address the concerns of the Examiner and to facilitate prosecution. See, Paper No.12, page 10, last paragraph to page 11, first paragraph. Examiner Marschel indicated that the enablement rejection would be obviated if the claim language was deleted.

## **II. The Restriction Requirement**

Applicants thank the Examiner for acknowledging Applicants timely traversal of the restriction requirement. Despite Applicants' traversal, the Examiner has rendered the restriction final. Applicants respectfully reserve the right to petition the restriction requirement under 37 C.F.R. § 1.144.

## **III. Amended Title of the Application**

The Examiner has asserted that the title of the invention is not adequately descriptive and has required Applicants to amend the title. See, Paper No.12, page 5, third paragraph. Applicants respectfully point out that the title has been amended to be more descriptive of the invention.

## **IV. New Matter Rejection Under 35 U.S.C. § 112, first paragraph**

The Examiner has rejected claims 25, 31, and 69-73 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. See, Paper No.12, pages 5-6. More particularly, the Examiner alleges at page 5, last paragraph that "[c]onsideration of the specification as filed has revealed that pages 58 and 59 describe SEQ ID NO:73 but not there or anywhere the specific truncated versions in the instant claims."

Applicants respectfully disagree and traverse.

Applicants respectfully point out that support for claims 25 and 31 can be found, for example, at page 150, line 31 to page 151, line 6. In addition, support for claims 69-73 can be found, for example, at page 88, lines 22-27; page 99, line 26 to page 100, line 6; page 103, lines 11-17; page 124, lines 10-17; and page 252, lines 17-21. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 25, 31,

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and 69-73 under 35 U.S.C. § 112, first paragraph. If the Examiner maintains that the subject matter of claims 25, 31, and 69-73 are new matter, Applicants respectfully request the Examiner to contact the undersigned to discuss the matter further.

**V. Rejection of Claims 11, 12, 16 and 24-73 under 35 U.S.C. § 101**

The Examiner has rejected claims 11, 12, 16, and 24-73 under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. See, Paper No. 12, pages 7-8. In particular, the Examiner states at page 7, last paragraph:

The specification states that the polypeptide of SEQ ID NO:73 compounds may be useful for the diagnosis and/or treatment of cancer as noted on page 59 of the instant specification. It appears that these asserted utilities are based on specific tissue distribution of polypeptides of gene number 23....No control tissue has been defined in said discussion for comparison.

Applicants respectfully disagree and traverse.

Preliminarily, Applicants respectfully point out that claims 11, 12, 16, 37-38, 44-45, 51-52, and 58-59 have been canceled rendering the rejection as to those claims moot. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claims 11, 12, 16, 37-38, 44-45, 51-52, and 58-59.

As pointed out by the undersigned in the interview with Examiner Marschel discussed *supra* and as attested to in the Declaration of George Komarsoulis Under 37 C.F.R. § 1.132 (Exhibit A), Applicants assessed the expression of the polynucleotides of SEQ ID NO:33 (which encode the polypeptide of SEQ ID NO:73) in tissues including, but not limited to, normal human adrenal gland tissue and human adrenal gland tumor tissue. Based on this assessment, no expression was observed in normal human adrenal gland tissue. In contrast, expression was observed in human adrenal gland tumor tissue. In view of the above and based on statements made by Examiner Marschel in the interview, Applicants believe that they have obviated the utility rejection. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 24-36, 39-43, 46-50, 53-57, and 60-73 under 35 U.S.C. § 101.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. § 101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged

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lack of utility of the claimed invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

**VI. Rejection of Claims 36-63 under 35 U.S.C. § 112, First Paragraph**

The Examiner has rejected claims 36-63 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. *See*, Paper No.12, pages 10-11. More specifically, the Examiner states at page 10, last paragraph through page 11, first paragraph:

Claims 36-63 either directly or via dependence cite the determination of a claimed polypeptide via specific antibody binding. Such specificity is well known to be determined by comparison to a control polypeptide....the choice of proper control polypeptides for specificity determination for the claims is clearly undue.

Applicants respectfully disagree, but in the interest of facilitating prosecution and in view of the interview with Examiner Marschel discussed *supra*, Applicants have amended independent claims 36, 43, 50, and 57 and canceled claims 37-38, 44-45, 51-52, and 58-59. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

**VII. Rejection of Claims 11, 12, 16, and 36-63 under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claims 11, 12, 16 and 36-63 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More particularly, the Examiner states at pages 11-12 of the Office Action:

Claim 11, 12, and 16 are vague and indefinite as to what is meant therein by the limitations 'variant' or 'species homologue.'

In addition, the Examiner alleges at pages 11-12:

Claims 40-42 cite 'the protein' of claim 36 which lacks clear antecedent basis in that only a polypeptide is cited in claim 36. Clarification via clearer claim wording is requested. This same unclear antecedent basis exists in claims 47-49, 54-56, and 61-63.

Further, the Examiner alleges at page 12, first full paragraph:

Claims 36-63 are vague and indefinite because these claims do not define the metes and bounds of the specificity in the claims.

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Applicants respectfully disagree, but in the interest of facilitating prosecution and in view of the interview with Examiner Marschel discussed *supra*, Applicants have amended claims 36, 40-43, 47-50, 54-57, and 61-63 and have canceled claims 11, 12, 16, 37-38, 44-45, 51-52, and 58-59. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 11, 12, 16 and 36-63 under 35 U.S.C. § 112, second paragraph.

**VIII. Objection to the Specification**

The Examiner has objected to the disclosure of the specification based on the fact that the specification at page 11, lines 12-43 contains single-spaced text. *See*, Paper No. 12, page 12. Applicants have deleted the single-spaced text from page 11, therefore, the objection has been obviated. Accordingly, Applicants respectfully request that the Examiner reconsider the objection to the disclosure in the specification.

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Conclusion

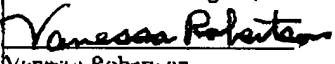
In view of the foregoing remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. A request is made to the Examiner to call the undersigned at the phone number provided below if any further action by Applicants would expedite allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: September 9, 2002

  
Janet M. Martineau (Reg. No. 46,903)  
Attorney for Applicants

Telecopier Transmission Certificate	
Send date: September 9, 2002	
I hereby certify that this paper and the attachments hereto are being sent by telecopier transmission to 703-308-4242 the above-indicated date addressed to:	
Examiner A. Marschel - Group 1631 U.S. Patent and Trademark Office Washington, D.C. 20231	
 Vanessa Robertson	<u>9-9-02</u> Date

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Enclosures  
KKH/JMM/SA/vr

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Ruben et al.

Application Serial No.: 09/661,453

Art Unit: 1631

Filed: September 13, 2000

Examiner: Marschel, A.

For: Secreted Protein HATCM08  
(as amended)

Attorney Docket No.: PZ038P1

**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Specification:**

The title paragraph found at page 1, line 1 has been amended as follows:

**[27 Human Secreted Proteins]**

**Secreted Protein HATCM08**

The paragraph found at page 11, spanning lines 12-43 has been deleted.

**In the Claims:**

Claims 11, 12, 16, 37-38, 44-45, 51-52, and 58-59 have been canceled.

The claims have been amended as follows:

36. (Once Amended) An isolated first polypeptide at least 90% identical to a second polypeptide consisting of amino acid residues 24 to 105 of SEQ ID NO:73 [, wherein said first polypeptide is capable of generating or selecting an antibody that specifically binds said second polypeptide].

40. (Once Amended) The [protein] polypeptide of claim 36 which further comprises a polypeptide sequence heterologous to SEQ ID NO:73.

41. (Once Amended) A composition comprising the [protein] polypeptide of claim 36 and an acceptable carrier.

42. (Once Amended) An isolated protein produced by the method comprising:

- (a) expressing the [protein] polypeptide of claim 36 by a cell; and
- (b) recovering said protein produced by the method.

43. (Once Amended) An isolated first polypeptide at least 90% identical to a second polypeptide consisting of the secreted portion of the polypeptide encoded by the HATCM08 cDNA contained in ATCC Deposit No. 203858 [, wherein said first polypeptide is capable of generating or selecting an antibody that specifically binds said second polypeptide].

47. (Once Amended) The [protein] polypeptide of claim 43 which further comprises a polypeptide sequence heterologous to the polypeptide encoded by the HATCM08 cDNA contained in ATCC Deposit No. 203858.

48. (Once Amended) A composition comprising the [protein] polypeptide of claim 43 and an acceptable carrier.

49. (Once Amended) An isolated protein produced by the method comprising:

- (a) expressing the [protein] polypeptide of claim 43 by a cell; and
- (b) recovering said protein produced by the method.

50. (Once Amended) An isolated first polypeptide at least 90% identical to a second polypeptide consisting of amino acid residues 1 to 105 of SEQ ID NO:73 [, wherein said first polypeptide is capable of generating or selecting an antibody that specifically binds said second polypeptide].

54. (Once Amended) The [protein] polypeptide of claim 50 which comprises a polypeptide sequence heterologous to SEQ ID NO:73.

55. (Once Amended) A composition comprising the [protein] polypeptide of claim 50 and an acceptable carrier.

56. (Once Amended) An isolated protein produced by the method comprising:

- (a) expressing the [protein] polypeptide of claim 50 by a cell; and



(b) recovering said protein produced by the method.

57. (Once Amended) An isolated first polypeptide at least 90% identical to a second polypeptide consisting of the complete polypeptide encoded by the HATCM08 cDNA contained in ATCC Deposit No. 203858 [, wherein said first polypeptide is capable of generating or selecting an antibody that specifically binds said second polypeptide]

61. (Once Amended) The [protein] polypeptide of claim 57 which further comprises a polypeptide sequence heterologous to the HATCM08 cDNA contained in ATCC Deposit No. 203858.

62. (Once Amended) A composition comprising the [protein] polypeptide of claim 57 and an acceptable carrier.

63. (Once Amended) An isolated protein produced by the method comprising:  
(a) expressing the [protein] polypeptide of claim 57 by a cell; and  
(b) recovering said protein produced by the method.